

## REMARKS

### I. Status Summary

Claims 1-6 were filed with the subject application. Claims 1-6 have been examined by the U.S. Patent and Trademark Office (hereinafter "the Patent Office"). Claims 1-6 presently stand rejected.

Claims 1-6 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Particularly, the Patent Office asserts that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-6 have also been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,467,793 to Ender.

Claims 1 and 3-5 have also been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,483,335 to Tornier.

Claims 1, 5, and 6 have been amended herein to clarify the phrase "an overhanging heel between the resilient body element and the trailing end of the flat surface". Support for such amendment can be found in claims 1, 5, and 6 as filed, as well as in Figures 7-9. Support is further found throughout the specification, for example, at page 16, lines 15-21; page 17, lines 1-4; and page 17, lines 12-14.

No new matter has been added.

Reconsideration of the application based on the amendments and arguments set forth herein is respectfully requested.

### II. The Drawings

Applicant respectfully requests that sheet 1, Figure 1, of the drawings as filed be withdrawn and canceled. The Figure 1 drawing of sheet 1 as filed was inadvertently included in the drawings as filed. Formal drawings for remaining Figures 1A - 1B, 2A - 2B, 3, 4A - 4B, 5A - 5D, 6A - 6B, 7A - 7B, 8A - 8B and 9A - 9B have now previously been submitted.

III. Response to the 35 U.S.C. § 112, First Paragraph, Enablement Rejection

Claims 1-6 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Particularly, the Patent Office asserts that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Without acquiescing in the contentions made by the Patent Office, and in an effort to expedite prosecution, claims 1, 5 and 6 have been amended. Specifically, claims 1, 5, and 6 have been amended herein to clarify the phrase “an overhanging heel between the resilient body element and the trailing end of the flat surface”. By amending claim 1, applicants have in effect amended claims 2-4 as well, since claims 2-4 depend from claim 1.

The phrase “an overhanging heel between the resilient body element and the trailing end of the flat surface” in claims 1, 5, and 6 has been amended to read “an overhanging heel between the location at which the resilient body element connects to the flat surface and the trailing end of the flat surface”. Such amendment is supported in the specification as filed by the phrase “resilient body element connected at one end thereof adjacent to but spaced apart from the trailing end of the flat surface” appearing in claims 1, 5, and 6 prior to the phrase now under discussion, and by Figures 7-9. Support is further found throughout the specification, for example, at page 16, lines 15-21; page 17, lines 1-4; and page 17, lines 12-14. In each of Figures 7-9 in the instant application, there is an occurrence of flat surface area between the location at which the resilient body element connects to the flat surface and the trailing end of the flat surface (numerals 30AA, 40AA, and 50AA in Figures. 7-9 respectively). This occurrence of flat surface area is clearly what applicants refer to as the “overhanging heel”.

Accordingly, applicant respectfully submits that the rejection of claims 1-6 under 35 U.S.C. § 112, first paragraph, has been addressed. Therefore, applicant respectfully requests that the instant 35 U.S.C. § 112, first paragraph, written description rejection be withdrawn at this time.

IV. Response to the 35 U.S.C. § 102(b) Rejections

Claims 1-6 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,467,793 to Ender. Claims 1 and 3-5 have further been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,483,335 to Tornier. Applicant traverses both rejections.

Applicant's invention as disclosed and claimed herein describes an intrafocal plate for securing bone fractures, wherein the plate is inserted into the fracture site. All of claims 1-6 describe an intrafocal plate which operates to secure bone fractures so that bone fragments do not shift away from an optimized position during recalcification. Such positioning of the plate is described throughout the specification. See, for example, the last line of page 4, where it is noted that "the pin end is intrafocally inserted into the fracture site". See also Figures 1, 4-7, and 9 of the instant invention, especially Figure 5, in which it is particularly easy to see that the device of the present invention is inserted into the fracture site.

According to the Patent Office, U.S. patent No. 4,467,793 by Ender (hereinafter "Ender") "discloses an intrafocal plate comprising..." (emphasis added). The Patent Office is respectfully reminded that an intrafocal device, by definition, is one that enters the broken bone at the fracture location. Represented in Figure 1 of Ender is an *intramedullary* device. The intramedullary device of Ender differs from the intrafocal apparatus of the instant invention in that the intramedullary device, as depicted in Ender Figure 1, is inserted into the bone longitudinally opposite from where the fracture is located. This very significant difference in structure and function would be well known to one skilled in the art such as an orthopaedic surgeon.

A further difference is that although the part of the Ender device labeled numeral "5" in Figure 1 somewhat resembles the elongated plate element of the present invention, the Ender numeral 5 device does not and cannot serve the function of stabilizing the fracture site because it is not located at the fracture site. Instead, Ender numeral 5 serves to provide a stable pathway for the insertion of nails and is referred to in the Ender disclosure as a "guiding channel for the bone nail or bone nails". See column 2, line 45 of Ender. Nowhere does Ender teach using the device depicted at number 5, Figure 1, as an intrafocal plate to stabilize a fracture in the manner of the elongated intrafocal plate element of the instant invention. Thus, Ender is completely

deficient in two important aspects of the current invention: Ender describes an intramedullary, not intrafocal, device and Ender does not provide an elongated plate element at the fracture site. It is well established as a matter of law that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). Clearly, in view of the differences inherent between an intramedullary device and applicant's intrafocal device, claims 1-6 of the instant invention cannot be anticipated by Ender. Ender does not teach the stabilizing elongated intrafocal plate element of the instant invention.

Summarily, Ender does not teach the intrafocal device of applicants' claimed invention and therefore cannot properly anticipate. Applicants respectfully submit that claims 1-6 are not anticipated by Ender. The applicants therefore request that the 35 U.S.C. § 102(b) rejection of claims 1-6 under Ender be withdrawn.

The Patent Office further asserts that claims 1 and 3-5 are anticipated by U.S. Patent No. 4,483,335 to Tornier (hereinafter "Tornier"). According to the Patent Office, "Tornier discloses in [F]igure 1 an intrafocal plate comprising..." Applicants again respectfully remind the Patent Office that the well-known term of art "intrafocal" device refers to a device inserted into a bone fracture site. Tornier, like Ender, describes an intramedullary device as depicted in Tornier Figure 1. Specifically, as represented in Tornier Figure 1, Tornier describes a device that is inserted into the end of the bone longitudinally opposite the broken end of the bone. As such, the "plate" described by Tornier cannot possibly serve to stabilize the bone fracture because the Tornier plate is not located at the bone fracture site. In contrast, the instant invention is characterized by the location of an elongated intrafocal plate element at the fracture site, where it functions to stabilize bone fragments.

Further, the Patent Office asserts that Tornier discloses an elongated plate having "an overhanging heel 8a". Applicant notes that there is no "overhanging heel" disclosed in Tornier similar to the overhanging heel of the present invention. The overhanging heel of the present invention is found between the location at which the resilient body element meets the elongated plate element at the trailing end of the

elongated plate element. An inspection of Tornier Figure 1 shows that there is no elongated plate surface area at all between the location at which the resilient body meets the elongated plate and the trailing end of the elongated plate. The elongated plate of Tornier extends in only one direction beyond the point at which the resilient body meets the elongated plate, and that is in the direction of the leading end. It would have to also extend toward the trailing end to define a "heel" and it does not do so. Thus, by definition, Tornier does not disclose or even suggest the overhanging heel of the instant invention for the simple reason that it would have no useful function in the Tornier device.

Nowhere does Tornier teach a device useful for stabilizing a fracture in the manner of the intrafocal plate of the instant invention. Thus, Tornier is completely deficient in three important aspects of the current invention: Tornier describes an intramedullary, not intrafocal, device; Tornier does not disclose the overhanging heel of the instant invention to help stabilize the fracture site; and Tornier does not provide an elongated plate element at the fracture site. It is well established as a matter of law that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). Clearly, in view of the differences inherent between Tornier's intramedullary device and applicant's intrafocal device, claims 1 and 3-5 of the instant invention cannot be anticipated by Tornier.

Tornier does not teach the intrafocal device of applicant's claimed invention and therefore cannot properly anticipate. Applicant respectfully submits that claims 1 and 3-5 are not anticipated by Tornier. The applicants therefore request that the 35 U.S.C. § 102(b) rejection of claims 1 and 3-5 under Tornier be withdrawn.

As noted above, each and every one of claims 1-6 of the present invention describes an intrafocal plate for securing bone fractures. Neither Ender nor Tornier teaches such an intrafocal device and so neither can possibly anticipate the instant invention. Applicant therefore requests that the 35 U.S.C. § 102 rejections under both Ender and Tornier be withdrawn.

CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that claims 1-6 of the present application are now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

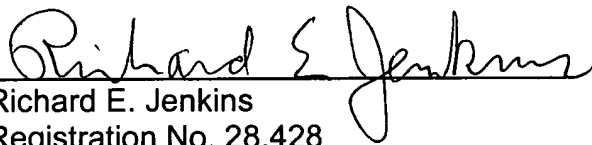
The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

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Title: MODIFICATION OF PERCUTANEOUS  
INTRAFOCAL PLATE SYSTEM  
Applicant(s): Laurence E. Dahners  
Atty. Dkt. No.: 421/75/2

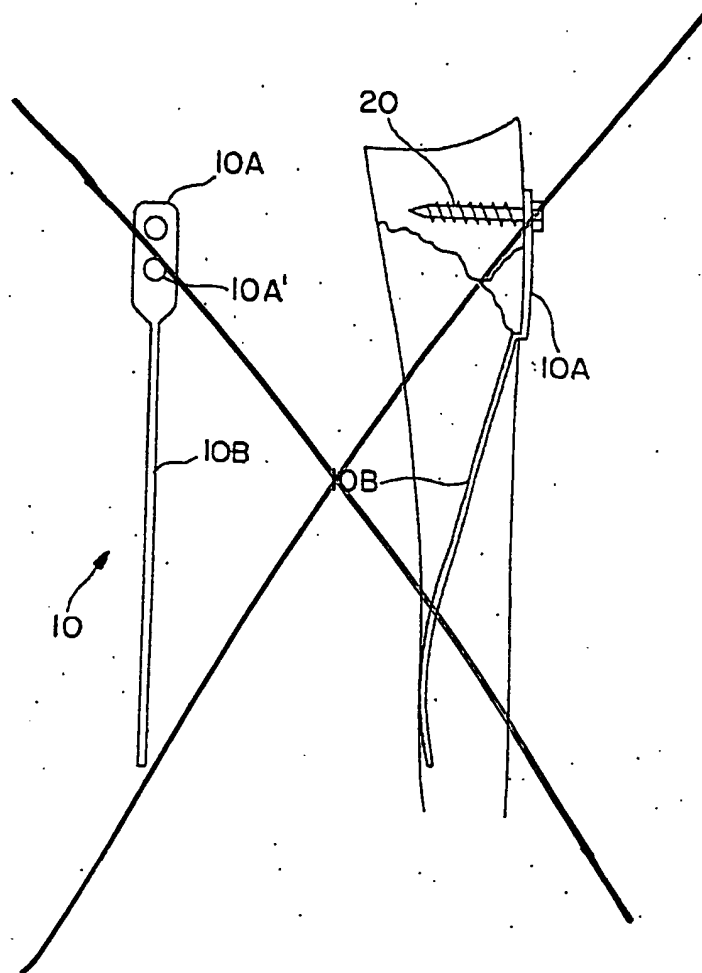


FIG. 1